



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,896	11/21/2003	John N. Nuss	PP-01677.006	1440

27476 7590 02/28/2007
NOVARTIS VACCINES AND DIAGNOSTICS INC.
CORPORATE INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
----------	--------------

1624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/719,896	Applicant(s) NUSS ET AL.	
	Examiner Venkataraman Balasubramanian	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27,31,32 and 37-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,12,17,18,23-27,37-42,44 and 45 is/are rejected.
- 7) ☒ Claim(s) 10, 11, 13-16, 19-22, 31, 32, 43 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, which included cancellation of claims 28-30, 33, 34 and amendment to claims 1, 23-26, 31 and 32, filed on 12/7/2006 has been entered.

Claims 1-27, 31, 32 and 37-46 are now pending.

In view of applicants' response, all 112 first and second paragraph rejections made in the previous office action have been either obviated due amendment to claims or rendered moot due to cancellation of rejected claims.

The following new rejections are applied to the currently pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 12 is an improper dependent claim as the scope of claim 12, which is dependent on claim 1, is outside the scope of claim 1. Note the Y and X together choice is not present in claim 1 on which claim 12 is dependent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 9, 23-27, 40-42, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawashima et al., US 6,251,900.

Kawashima et al., teaches several pyrimidine compounds substituted with benzimidazole and morpholine useful for treating lung and breast cancer, which include compounds, composition and method of use embraced in the instant claims. See formula I. Note when Y is N, X is CR₇ and R₃ is morpholino group, the compounds taught by Kawashima et al., are also generically embraced in the instant claims. See column 3, lines 66-67, column 4 and column 5 for various pyrimidine compounds. See entire document.

Claims 1, 2, 4, 5, 7-9, 23-27, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Konno et al., US 5,786,355.

Konno et al., teaches several 2,4-aryl-pyrimidine compounds useful for treating lung and breast cancer, which include compounds, composition and method of use embraced in the instant claims. See formula I. Note when R is piperidine, piperazine or

Art Unit: 1624

morpholine and Ar is an aryl group, the compounds taught by Konno et al., are also generically embraced in the instant claims. See column 32, examples 21-23 or Table 6 (column 45-48) for various pyrimidine compounds.

Claims 1-3, 5, 9, 23-27, 40-42, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Strekowski et al., US 4,929,726. CAPLUS Abstract is also provided.

Strekowski et al., teaches several pyrimidine compounds substituted with benzimidazole and morpholine useful for amplifying the effect of anticancer agents such as bleomycin, which include compounds, composition and method of use embraced in the instant claims. See formulae shown in column 12-14. Note with the given definition of various R and R₂ groups, the compounds taught by Strekowski et al., are also generically embraced in the instant claims. See column 14-17 for compounds.

Claims 1-8, 23, 40, 42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Narr et al., DE 2341925.

Narr et al., teaches several 2,4,5,6-tetrasubstituted pyrimidine compounds useful as antithrombotics, which include compounds, composition and method of use embraced in the instant claims. See formula I. Note with the given definition of various R₁, R₂, R₄ and R₃ groups, the compounds taught by Narr et al., are also generically embraced in the instant claims. See entire document for details of the invention. Especially see page 83, example 135, page 89, example 157 and page 90, example 159 for some examples of compounds made. See also page 89, example 156.

Art Unit: 1624

Claims 1, 2, 4, 5, 7-9, 23, 37, 40-42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Sharma et al., Indian Journal of Chemistry, Section B: Organic Chemistry including Medicinal Chemistry 38B(8), 966-968, 1999. CA 132:207818, 2000. CAPLUS Abstract provided.

See 14 compounds shown in the CAPLUS Abstract.

Claims 1, 2, 4, 5, 7-9, 23, 37, 40-42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kothari et al., Indian Journal of Heterocyclic Chemistry, 8(4), 285-288, 1999. CA 131: 257250, 1999. CAPLUS Abstract provided.

See 7 compounds shown in the CAPLUS Abstract.

Claims 1-3, 5, 6, 23 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Mokrosz et al., Archiv der Pharmazie, 328(9), 659-666, 1995. CA 124: 223, 1995. CAPLUS Abstract provided.

See 17 compounds shown in the CAPLUS Abstract.

Claims 1, 23 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Sukhwai et al., Indian Journal of Heterocyclic Chemistry, 4(1), 67-68, 1994. CA 122: 105796, 1995. CAPLUS Abstract provided.

See 4 compounds shown in the CAPLUS Abstract.

Claims 1, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikhaleva et al., Khimiya Geterotsiklicheskikh Soedinenii 6, 621-626, 1979. CA 91: 107951, 1979. CAPLUS Abstract provided.

See 2 compounds shown in the CAPLUS Abstract.

Art Unit: 1624

Claims 1-3, 5, 6, 9, 23, 40-42, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Tani et al., JP 49021148, CA 82: 140173, 1975. CAPLUS Abstract provided.

See 3 compounds shown in the CAPLUS Abstract.

Claims 1, 23 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Mamaev et al., Reaktsionnaya Sposobnost Organicheskikh Soedinenii 5(3), 824-837, 1968. CA 70: 76976, 1969. CAPLUS Abstract provided.

See 2 compounds shown in the CAPLUS Abstract.

Claims 1, 2, 5-9, 23, 40-42, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Falco et al., British Journal of Pharmacology and Chemotherapy, 6, 185-200, 1951. CA 46: 27482, 1952. CAPLUS Abstract provided.

See the compound shown in the CAPLUS Abstract.

Claims 1, 23 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Andrisano, Bollettino Scientifico della Facolta di Chimica Industriale di Bologna, Volume Date 1944-1947, 5, 48-51. CA 44: 19897, 1950. CAPLUS Abstract provided.

See the compound shown in the CAPLUS Abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1624

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 17, 18, 23, 38, 40-42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Narr et al., DE 2341925.

Teachings of Narr et al. as discussed in the above 102 rejection is incorporated herein. As noted above, Narr et al., teaches several 2,4,5,6-tetrasubstituted pyrimidine compounds useful as antithrombotics, which include compounds, composition and method of use embraced in the instant claims. See formula I. Note with the given definition of various R₁, R₂, R₄ and R₃ groups, the compounds taught by Narr et al., are also generically embraced in the instant claims. See entire document for details of the

Art Unit: 1624

invention. Especially see page 83, example 135, page 89, example 157 and page 90, example 159 for some examples of compounds made. See also page 89, example 156.

Narr et al. differs from the instant claims in exemplifying only few pyrimidine compounds bearing instant Y-X, W, R₁ and R₂ choices.

However, Narr et al. teaches equivalency of those compounds (examples 1-225) taught in pages 10-111 with those generically recited in pages 1-3 for formula I.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds using the teachings of Narr et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Allowable Subject Matter

Claims 10, 11, 13-16, 19-22, 31, 32, 43 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable, barring finding of any prior art in a subsequent search, if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any

Art Unit: 1624

inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).


Venkataraman Balasubramanian

2/26/2007